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Clinical success rate of percutaneous management in the thrombosed hemodialysis graft at King Chulalongkorn Memorial Hospital

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Background : *Percutaneous thrombolysis can be the effective method for treatment of the hemodialysis graft.*

Objective : *To retrospectively determine the clinical success rate of percutaneous management in thrombosed hemodialysis graft, the primary and secondary patency periods of graft after percutaneous management and complication at King Chulalongkorn Memorial Hospital from 1 January, 2007 to 30 November, 2014.*

Materials and Methods : *Twenty-nine PTFE grafts in 29 patients were referred to Intervention Radiology Unit for the percutaneous management of thrombosed hemodialysis graft. Angiographic reports and hospital medical records were analyzed for the clinical success rate, procedural record, angiographic finding, complication, and patency period of the graft after treatment. Clinical success rate was determined by complete graft restoration with a palpable thrill and return to normal dialysis for at least one session. Patency period were calculated with Kaplan-Meier method analysis to estimate graft survival probability with standard deviation.*

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Results : *Clinical success rate was achieved in 28 of 29 cases (96.55%). Neither major nor minor complication occurred. After successful percutaneous thrombolysis, 3 of 28 were loss to follow up. Consequently, 25 grafts were evaluated for patency periods with the mean follow-up period of 593.6 ± 79.5 days (437.7 - 749.5 days). Mean patency period (mean survival time) after the 1st percutaneous thrombolysis of all 25 grafts were calculated to 263.6 ± 49.4 days (166.9 - 360.7 days).*

Conclusion : *Percutaneous thrombolysis is a safe and effective mean for treatment of thrombosed hemodialysis graft at King Chulalongkorn Memorial Hospital. Our success rate is comparable to the National Kidney Foundation Dialysis Outcome Quality Initiative.*

Keywords : *Thrombosed hemodialysis graft, percutaneous thrombolysis, patency periods.*

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ที่มาและความสำคัญ : *เนื่องจากการรักษาหลอดเลือดเทียมที่ใช้ฟอกไตอุดตันจากลิ่มเลือดด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือด เป็นการรักษาที่ให้ประโยชน์และได้ผลดีในหลายประการ*

วัตถุประสงค์ : *อัตราความสำเร็จของการรักษาหลอดเลือดเทียมที่ใช้ฟอกไตอุดตันจากลิ่มเลือดด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดในโรงพยาบาลจุฬาลงกรณ์ตั้งแต่เดือนมกราคม พ.ศ. 2550 ถึง 30 พฤศจิกายน พ.ศ.2557*

รูปแบบการวิจัย : *การศึกษาข้อมูลย้อนหลัง*

สถานที่ทำการศึกษา : *ภาควิชารังสีวิทยา โรงพยาบาลจุฬาลงกรณ์*

ตัวอย่างและวิธีการศึกษา : *ผู้วิจัยได้ทำศึกษาข้อมูลย้อนหลังในผู้ป่วย 29 ราย โดยแต่ละคนมีหลอดเลือดเทียมที่ใช้ฟอกไตอุดตัน 1 หลอด ผู้ป่วยเหล่านี้ถูกส่งตัวมารักษาที่หน่วยรังสีร่วมรักษาโรงพยาบาลจุฬาลงกรณ์ ผู้วิจัยได้ศึกษาข้อมูลอัตราความสำเร็จวิธีการรักษาภาวะแทรกซ้อนและระยะเวลาการคงอยู่ของหลอดเลือดเทียมที่ใช้ในการฟอกไต หลังการรักษาด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดจากใบบันทึกการรักษาด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดและเวชระเบียนของผู้ป่วย โดยอัตราความสำเร็จประเมินจากสามารถคลำเจอการเต้นของหลอดเลือดเทียม และหลอดเลือดเทียมสามารถนำมาใช้ฟอกไตได้อีกอย่างน้อย 1 ครั้ง ระยะเวลาการคงอยู่ของหลอดเลือดเทียมที่ใช้ในการฟอกไตถูกคำนวนจากวิธี Kaplan-Meier เพื่อวิเคราะห์ความน่าจะเป็นของการอยู่รอดหลอดเลือดเทียม ร่วมกับการคำนวนค่าเบี่ยงเบนมาตรฐาน*

ผลการศึกษา : *มีผู้ป่วย 1 รายใน 29 รายไม่ประสบความสำเร็จจากการรักษาด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดอัตราความสำเร็จของการรักษาหลอดเลือดเทียมที่ใช้ฟอกไตอุดตันจากลิ่มเลือดด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดจึงคิดเป็น 96.55% หลังการรักษามีผู้ป่วยจำนวน 3 คนไม่มาตรวจติดตามการรักษา ดังนั้นจึงมีผู้ป่วยจำนวน 25 รายที่ได้รับการประเมินระยะเวลาการคงอยู่ของหลอดเลือดเทียมที่ใช้ในการฟอกไตต่อ โดยมีค่าเฉลี่ยของระยะเวลาการตรวจติดตามผู้ป่วยคิดเป็น 593.6 ± 79.5 วัน (437.7 - 749.5 วัน) และมีค่าเฉลี่ยของระยะเวลาการคงอยู่ของหลอดเลือดเทียมที่ใช้ฟอกไตอุดตันหลังการรักษาด้วยวิธีกาสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดคิดเป็น 263.6 ± 49.4 วัน (166.9 - 360.7 วัน)*

สรุป : *การรักษาหลอดเลือดเทียมที่ใช้ฟอกไตอุดตันจากลิ่มเลือดด้วยวิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือดเป็นวิธีที่ปลอดภัยและให้ผลดีในโรงพยาบาลจุฬาลงกรณ์อัตราความสำเร็จเทียบเท่ากับอัตราความสำเร็จที่รายงานโดยองค์กรควบคุมคุณภาพและผลลัพท์การฟอกไตแห่งชาติ*

คำสำคัญ : *หลอดเลือดเทียมที่ใช้ฟอกไตอุดตันจากลิ่มเลือด, วิธีการสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือด, ระยะเวลาการคงอยู่ของหลอดเลือดเทียมที่ใช้ฟอกไตอุดตันหลังการรักษาด้วยวิธีกาสลายลิ่มเลือดผ่านการสวนเข้าหลอดเลือด.*

Currently, there are many chronic hemodialysis patients around the world requiring permanent vascular access for hemodialysis. Native arteriovenous (AV) fistula and AV polytetrafluoroethelene (PTFE) graft are two most common forms of permanent hemodialysis access.[1] PTFE graft is usually the second alternative for permanent vascular access. Although AV fistula is always the first choice, it is impossible to create AV fistula in every patient from the following reasons[1]:

- Failure of AV fistula or exhausted superficial vein;[2]
- Lack of proper vessels particularly in old patients with peripheral vascular disease, diabetes or damaged vessel due to venipuncture;[3]
- Requiring immediate cannulation with avoidance of central venous catheter access;[4]
- Inability of the children to tolerate multiple venipuncture related with AV fistula.[4]

From the recent data, the incidence of PTFE graft creation is increasing, especially in the USA[5], as it is more convenient to be created by surgery, requiring shorter time to mature (only 2 - 3 weeks) and provides larger area for cannulation. [6]

Graft materials

Prosthetic AV grafts are categorized as biologic or synthetic.[7] There are limitations of biologic graft usage according to its cost, difficulty in production, difference in size and quantity.[7] PTFE graft is more predominate than the other biologic and synthetic matters in view of lowering risk of graft infection, low thrombogenesis, low tissue reactivity, prolonged patency and improved surgical management. [8 - 10]

Eighty percents of PTFE graft failure is caused by thrombosis[11], and more than 90% of thrombosed grafts show the underlying venous outflow stenosis.[11] The other causes of graft failure are dehydration, hypotension and kinking during sleep and excessive compression after venipuncture or dialysis.[7] In case of uncorrectable permanent graft failure occurs, shifting to use peritoneal dialysis or less optimal lower extremities graft or a dialysis catheter is needed. Lack of hemodialysis access inevitably leads to death. Consequently, each permanent hemodialysis accesses have to be preserved as long as possible.[12]

The neointimal hyperplasia at anastomotic site and proximal vein is account for the underlying stenosis.[7] The including reasons are compliance mismatch between vein and graft, boundary layer disintegration, increased low shear stress and high flow velocity of the blood at anastomosis.[13, 14] Smooth muscle proliferation, extracellular matrix production and angiogenesis are demonstrated as the pathogenesis for neointimal hyperplasia lesion of the venous anastomosis. [1] The venous intimal hyperplasia appears to play an important role in dialysis access graft stenosis. [7]

As thrombosis and stenosis are common complications of dialysis access graft, there is much attempt to find appropriate managements for these conditions. The surgical treatment has been traditionally performed for the treatment of dialysis access failure. [15 - 17] However, over the decades, percutaneous techniques have been mainly used for hemodialysis access dysfunctions including balloon angioplasty, pharmacomechanical thrombolysis, atherectomy, stent deployment and mechanical thrombolysis. [12]

As the surgical treatment shows significant infection risk, patient discomfort and longer stay in the hospital if admission is needed. [18] While the percutaneous mean shows low-risk minimal invasive procedure[12] and can be done in outpatient basis with immediate return to hemodialysis treatment and avoiding need for temporary subclavian vein catheter placement, leading to favorable consequence.[19] In addition, the percutaneous technique can preserve the anatomy of vascular access and thus it can be performed repetitively.[20, 21] In case the further surgical treatment is needed, the latest angiography helps guiding the surgery, revealing the nature of underlying graft and associated supplying arteries or draining central veins.[12]

From the great benefits mentioned above, the percutaneous thrombolysis has a role in initial treatment of dysfunctional hemodialysis access in the present and the surgical treatment is reserved for unsuccessful percutaneous procedure or early recurrence.[12] Although percutaneous method has been increasingly used in the present but surgical method should beconsidered for treating the persistent anatomical abnormalities, severe aneurysmal dilatation, graft infection, patients having risk of bleeding or contraindication for thrombolysis.[22]

At our hospital, we have performed pharmacomechanical thrombolysis using recombinant tissue plasminogen activator in conjunction with the angioplasty for correcting the underlying stenosis. This technique has been proved a promising method for correction thrombosed hemodialysis graft.[19]

According to the pool data cited in “Quality improvement guideline for percutaneous management of the thrombosed or dysfunctional dialysis access” , reported clinical success rate and patency rate of the thrombosed graft associated with stenosis after treatment with thrombolysis or mechanical thrombectomy.[23] The results gathered from the former studies were varied. [19, 21, 24 - 32] The clinical success rate ranged 75 - 94%, at 6 - month, 12-month primary patency rates ranged 37 - 54%, 18 - 39%, respectively and at 6-month, 12-month secondary patency rate ranged 62 - 80% and 57 - 89%, respectively.[23] Furthermore, the complication rate has been mentioned and classified as major or minor complication. [27, 30, 33,34] This guideline has also been assigned the threshold levels for the treatment outcome.

The purpose of this study was to determine the clinical success rate of percutaneous management in thrombosed hemodialysis graft, the primary and secondary rate of grafts and the complication after percutaneous management in our hospital.

Materials and Methods

Study groups

From 1 January 2007 to 30 November 2014, 29 PTFE grafts in 29 patients were referred to Intervention Radiology Unit at King Chulalongkorn Memorial Hospital (KCMH) for the percutaneous management of thrombosed hemodialysis graft. The patients were presented with clinical manifestation of thrombosed grafts and confirmed diagnosis by Doppler ultrasound. Exclusion criteria included patients having hypercoagulable state, severe cardiac risk factor and pulmonary disease, suspected infection, anatomical anomaly of graft, contraindication to recombinant tissue plasminogen activator (rt-PA)and contrast media injection as well as the

technical limitations such as unsuitable venous outflow or contrast media extravasation after pretreatment evaluation with angiographic study. We performed percutaneous thrombolysis with angioplasty in 25 patients and thrombolysis and endovascular stenting for central venous stenosis in one patient.

Technical procedure of percutaneous management for thrombosed hemodialysis graft in KCMH.

All grafts were treated with thrombolysis and percutaneous transluminal angioplasty (PTA) technique as follows:

1. The patient was under physiologic monitoring. The access site was prepared and draped in the usual sterile fashion. Local anesthesia at the puncture sites with 2% Xylocaine injection was done.

2. Under ultrasound guidance, an 18-G sheath needle was used for puncture into the proximal graft close to arterial anastomosis in antegrade direction, then a 0.035" Terumo guide wire was inserted and confirmed position under fluoroscopic guidance. Then a 6Fr introducer sheath was installed over the guide wire.

3. Small amount of contrast was injected through the introducer sheath in order to confirm graft occlusion. If there was contrast extravasation from graft on initial angiogram, then the procedure was aborted and patient was excluded from study.

4. An attempt to pass a 0.035" Terumo guide wire across the venous anastomosis was performed. If not initially success, a 5Fr catheter was inserted into the graft close to venous anastomosis and then contrast was injected via catheter to evaluate venous outflow. If the venous outflow was considered to be unsuitable or may not be possible to re-opened, then the procedure was aborted. The patient was excluded from the study if thrombolysis was not given.

5. With a 0.035" Terumo guide wire cross the venous anastomosis, another 6F introducer sheath was installed at distal graft close to venous anastomosis in retrograde direction.

6. A 6Fr guiding catheter connected to 20-ml Syringe was inserted into each introducer sheaths in order to performed clot aspiration by using negative pressure.

7. A 5Fr catheter was inserted with its tip placed close to arterial and venous anastomoses. The Actilyse® (rt-PA) were bolusly administered via the sheaths and catheter(s) into the graft. Maximum dose of Actilyse® wasusually limited at 10 mg. Heparin 2,500 - 3,000IU was given intravenously during the procedure.

8. After thrombolytic drug administration and clot aspiration, percutaneous transluminal angioplasty(PTA) was performed. Balloon catheter was inserted via the proximal sheath, then angioplasty was initiated from the proximal through the distal limb of the graft and across the venous anastomosis to macerate any residual thrombus.

9. Arterial inflow was then reestablished by the same manner. Angioplasty across the arterial anastomosis might be gently performed in case of impacted clot near anastomosis, simultaneous with thrombolytic drug administration.

10. Evaluation of the arterial anastomosis, graft, venous outflow and central veins was performed angiographically. Any visualized residual thrombus wastreated repeatedly with balloon angioplasty as needed.

11. In cases of recoil or restenosis of the

venous anastomosis, further dilation with prolonged inflation and/or a larger balloon diameter was performed. If additional central venous stenosis was identified, it was also treated with balloon angioplasty with or without stent placement as needed.

12. When patent graft and outflow veins were established, then the catheters and sheaths were removed. Hemostasis was obtained by Woggle technique.

13. The patient was followed up by physical examination and color Doppler ultrasound in the next morning. Removal of the hemostasis devices was done within 24 – 48 hours.

Data collection and analysis

Procedural records, angiographic reports, dialysis records and hospital medical records were retrospectively analyzed for technical details of the procedures, angiographic findings, complications, and graft patency after treatment. Data collection includedpatients' demographic data, access descriptions, angiographic methods and outcomes of percutaneous management (short-term and long-term results), periods of patency and complication. If there were more than one creations of AV graft in the same patient, the data were recorded separately and patency rates of each grafts were determined separately.

The clinical success rate was determined by complete graft restoration with a palpable thrill and return to normal dialysis for at least one session. Patency of each grafts after percutaneous management was followed. The patency period were summarized and calculated with Kaplan-Meier method analysis to estimate graft survival probability with standard deviation.

Definition

This definition is similar to those recommended by the Society of Interventional Radiology Technology Assessment Committee in published reporting standards, 2003.[35]

Percutaneous management is defined as percutaneous thrombolysis with/without angioplasty with/without stent placement.

Clinical success is defined as complete graft restoration with a palpable thrill and return to normal dialysis for at least one session.

Post-intervention primary patency is defined as a period of uninterrupted patency from the intervention until the first next thrombosis or re-intervention.

Post-intervention secondary patency is defined as a period after intervention till the surgical treatment or discontinuing any treatments such as loss to follow up, kidney transplantation or death, etc. The number and the technique of the percutaneous management used for maintaining the secondary patency are presented.

Complication is defined as any events associated with the intervention procedure categorized as major complication and minor complication. The major complications include prolonged admission for treatment, permanent adverse consequent and death. While the minor complication causes only short stay in hospital for observation without adverse sequelae.

Demographic data

Thirteen patients were male, and sixteen patients were female. Patient ages ranged from 21 to 85 years with the mean age of 65.4 years. The

comorbidities of these patients and types of surgical graft anastomoses are demonstrated as follows;

Comorbidities of the patients

Hypertension	23
DM	17
CA bladder	1
Dyslipidemia	5
AF	1
Coronary artery disease	3
CA colon	2
Stroke	3
Gout	1
Parkinsonism	1
Duodenal ulcer	1

Surgical graft anastomosis

Left brachiocephalic	15
Left brachiobasilic	5
Left radiocephalic	1
Right brachiocephalic	7
Right brachiobasilic	1

Results

Clinical success rate was achieved in 28 of 29 cases (96.55%) without minor and major complications. Amount of Actilyse® used for thrombolysis ranged from 3 to 20 ml with mean amount 8.4 ml. The balloon angioplasty catheter ranged from 6Fr-8Fr, commonly used 6Fr. One graft failed to treat percutaneous thrombolysis due torestenosis of the venous outflow immediately after angioplasty. Post-percutaneous thrombolysis angiography of the successful cases showed residual stenosis in 1 case and central vein stenosis in one case.

As for patients with central vein stenosis, an 80-year-old male with thrombosed left brachiobasilic graft that had stenosis of left brachial vein and left subclavian vein to SVC junction. A 6Fr×40-mm balloon catheter was used for angioplasty of the central vein stenotic segment. Then, 3 stents (10 × 60 mm) were placed from subclavian vein to SVC junction. After stenting, improvement of the stenotic segments without residual significant stenosis was obtained. Good patency and blood flow was established. As for one graft that had residual stenosis, the graft was continuously followed up with patent lumen and not requiring re-intervention until the study end point.

After successful percutaneous thrombolysis, 3 of 28 were loss to follow up. Consequently, 25 grafts could be further evaluated for patency period. The mean follow-up time was calculated to 593.6 ± 79.5 days (437.7 - 749.5 days).

Of 25 grafts, 17 were further underwent the secondary percutaneous treatments for re-stenosis or re-thrombosis of the same grafts. Nine (9/17) patients had venous anastomosis stenosis, which were successfully treated by angioplasty. Eight (8/17) patients had re-thrombosis of the graft which were successfully treated by percutaneous thrombolysis. Of 17 grafts, 13 were patent until the study end point. While 4 patients were underwent permanent catheter installation (2/4), new graft placement (1/4) and renal transplantation (1/4) during the follow-up period. Mean patency of the secondary intervention was not able to be calculated due to insufficient follow-up period after treatment.

Of 25 grafts, 4 met the secondary patency criteria without any re-intervention. Two patients died of chronic kidney disease and acute myocardial

infarction. Two patients had permanent graft failure underwent permanent catheter installation.

Of 25 grafts, 4 were still patent without any re-intervention until the study end point.

The mean patency periods (mean survival time) after the first percutaneous thrombolysis of all 25 grafts were calculated to 263.6 ± 49.4 days (166.9 - 360.7 days) as demonstrated in Figure 1.

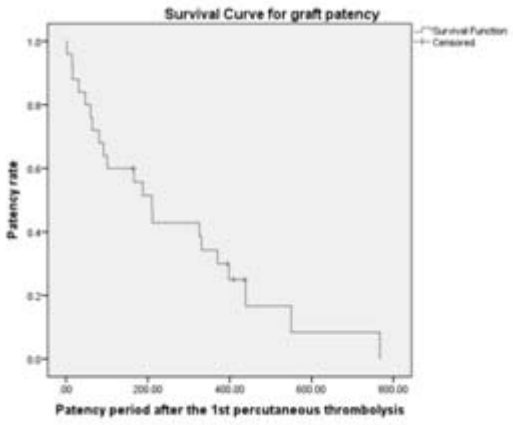

Figure 1. Survival curve for graft patency after the first percutaneous thrombolysis.

Twenty-five patients were divided into two groups regarding to the primary patency period ≤ 6-month and > 6-month after thrombolysis. The parameters including amount of Actilyse® and size of balloon angioplasty catheter were assessed in each group. The amount of the Actilyse® used in ≤ 6-month patency period group was 13.5 ml while the amount of the Actilyse® used in > 6-month patency period group was 12.5 ml. There was no significant difference in the amount of Actilyse® used in thrombolysis between the two groups (*P*-value = 0.72). The sizes of balloon angioplasty catheter also showed no significant difference between these two groups (*P*- value = 0.27).

Discussion

At our hospital total number of 29 procedures of percutaneous thrombolysis for thrombosed AV graft were performed over 8 years, representing the lower incidence of PTFE graft creation in KCMH as compared with other studies from the USA.[5]

The results of our study indicated that percutaneous thrombolysis of the thrombosed hemodialysis grafts at KCMH could be performed reliably and safely with the clinical success rate of 96.55% without minor and major complications. Our success rate was comparable to the National Kidney Foundation Dialysis Outcome Quality Initiative that recommended the clinical success rate ranged 75 - 94% .[23] However, our study was limited by its retrospective nature, and the number of patients included in this study was small, implying that the study may be underpowered for the evaluation of clinical success rate. Furthermore, some cases that were aborted without procedural attempt because the venous outflow was considered unsuitable or not be possible to re-open. Consequently, the number of cases with treatment failure might be underestimated due to selection bias.

The mean patency period (mean survival time) after the first percutaneous thrombolysis of all 25 grafts in this study were calculated at 263.6 ± 49.4 days (166.9 - 360.7 days) which can be extrapolated the patency period of the graft in the further percutaneous thrombolysis in our hospital. The 6-month and 12-month patency periods were 56% and 34% comparable to the 6-month and 12-month patency periods of 37 - 54% and 18 - 39% reported in the Quality Improvement Guideline for Percutaneous Management of the Thrombosed Hemodialysis Graft. [23]

At present, pulsed-spray pharmacomechanical thrombolysis has become a technique of choice for percutaneous thrombolysis as its consistency, rapidity and high success rate.[19] The procedure involved the use of multiple small pulses of highly concentrated urokinase or t-PA, which are forcefully sprayed throughout the thrombus via multiple tiny sideholes or side slits catheters.[19] This method showed a shorter time[19]and lower t-PA dose [36] required for thrombolysis. However, according to the expense of the pulse spray injector, our institution still manually administered Actilyse® (rt-PA) via the sheaths and catheter(s) into the graft, resulting in higher doses of Actilyse® required for the procedure as compared with pulsed-spray technique. We also used 2,500 – 3,000IU heparin as an adjunct for the thrombolysis less than the amount of 5,000 - 7,000 IU heparin commonly used the in pulsed-spray technique. [19]

In our study, there was neither major nor minor complication. This might be resulting from our exclusion criteriain cluding patients having hypercoagulable state, severe cardiac risk factors and pulmonary disease, suspected infection, anatomical anomaly of graft and contraindication to recombinant tissue plasminogen activator (rt-PA). We did not find any remote bleeding, perigraft hematoma, graft extravasation or clot embolization as in other studies.[19]

We successfully performed procedures by using only standard percutaneous balloon angioplasty catheters, the size ranging from 6Fr – 8Fr. Consequently, the risk of venous rupture or dissection which was reported in the peripheral cutting balloon technique [37], was not our issue.

Central venographyisis recommended for complete assessment of the outflow and central veins.[38] It is necessary to rule out the presence of a central stenosis caused by previous insertion of hemodialysis catheters. At our institution, wesimultaneously attempted to correct central vein stenosis and the thrombosed grafts as one plausible hypothesis showed that central vein stenosis might result in hemodynamic changes of the thrombosed graft, leading to early re-thrombosis.[38]

Conclusion

Percutaneous thrombolysis can be an effective method for percutaneousthrombolysis of the hemodialysis graft. However, there were limitations in our study due to the small number of thrombosed hemodialysis graft underwent percutaneous thrombolysis and the follow-upperiod should be prolonged to verify the long-term outcome and patency period after the re-intervention.

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